Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2003 list were published in the Federal Register in May 2003.

New Approvals

NADA Number: 141-199

Trade Name:	Rimadyl® Injectable
Ingredients:	Carprofen
Sponsor:	Pfizer, Inc.
Approval Date:	March 3, 2003
Status:	Prescription only
Route:	Subcutaneous
Species:	Dogs
Drug Form:	Liquid (solution)
Concentration:	50 milligrams per milliliter
Indications:	For the relief of pain and inflammation associated with osteoarthritis.
Patent Number:	4,882,164 Expiration date: February 19, 2008
Exclusivity:	3 years

21CFR 522.312

NADA Number: 141-217

Trade Name:	Neutersol®
Ingredients:	Zinc Gluconate Neutralized by Arginine
Sponsor:	Technology Transfer, Inc.
Approval Date:	March 17, 2003
Status:	Prescription only
Route:	Intratesticular
Species:	Dogs
Drug Form:	Liquid (solution)
Concentration:	13.1 milligrams per milliliter
Indications:	For chemical sterilization in 3 to 10 month old male puppies.
Patent Number:	4,937,234 Expiration date: August 10, 2008 5,070,080 January 30, 2009
Exclusivity:	5 years

21CFR 522.2690 & 510.600

ANADA Number: 200-347

Pioneer Product:	055-060
Trade Name:	Penicillin G Potassium USP
Ingredients:	Penicillin G potassium
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	January 22, 2003
Status:	Over-the-counter
Route:	Oral, drinking water
Species:	Turkeys
Drug Form:	Powder (soluble)
Concentration:	0.5 billion I.U. per 48 ounces
Indications:	For the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.
Tolerance:	21CFR 556.519 Penicillin: A tolerance of 0.01 part per million is established for residues in the uncooked edible tissues in turkeys.
Withdrawal:	1 day

21CFR 520.1696b

Supplemental Approvals

NADA Number: 128-620

This supplemental application provides for a change to over-the-counter marketing status for the oral use of fenbendazole suspension in goats. (NOTE: Goats will be removed from Panacur® label and added to the Safe-guard® label.)

Trade Name:	Safe-Guard®
Ingredients:	Fenbendazole
Sponsor:	Intervet, Inc.
Approval Date:	February 13, 2003
Status:	Over-the-counter
Route:	Oral
Species:	Goats
Drug Form:	Liquid (suspension)
Concentration:	100 milligrams per milliliter
Indications:	For the removal and control of stomach worms (adults) *Haemonchus contortus* and *Teladorsagia circumcincta*.
Tolerance:	21CFR 556.275 Fenbendazole: The tolerance for parent fenbendazole (the marker residue) is 0.8 part per million in liver and 0.4 part per million in muscle.
Withdrawal:	6 days Milk- not established

21CFR 520.905a

NADA Number: 139-236

This supplemental application provides for a more concentrated dosage (300 milligrams per milliliter) for use in members of the family Cervidae to produce a state of sedation accompanied by a shorter period of analgesia.

Trade Name:	Cervizine 300
Ingredients:	Xylazine hydrochloride
Sponsor:	Lloyd, Inc
Approval Date:	February 10, 2003
Status:	Prescription only
Route:	Intramuscular
Species:	Cervidae
Drug Form:	Liquid (solution)
Concentration:	300 milligrams per milliliter
Indications:	To be used in Cervidae (fallow deer, mule deer, sika deer, white-tailed deer and elk) when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia.
Patent Number:	4,614,798 Expiration Date: September 30, 2003

21CFR 522.2662

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-034

This supplemental application provides for use of bambermycins Type A Medciated Articles to make Type B and C feeds at a rate of 10 to 40 milligrams bambermycins per head per day.

Trade Name:	Gainpro®
Ingredients:	Bambermycins
Sponsor:	Intervet, Inc.
Approval Date:	February 10, 2003
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers)
Drug Form:	Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration:	10 grams of bambermycins activity per pound of Type A Medicated Article.
Indications:	For increased rate of weight gain in pasture cattle.
Tolerance:	Not established.

21CFR 558.95

Addition of Sponsor

Technology Transfer, Inc.
33 East Broadway, Suite 190
Columbia, MO 65203
Drug labeler code: 067647

Addition of Patent Number

NADA Number: 141-189

Patent Number: 6,340,671
Expiration Date: January 22, 2019

Technical Amendment

The Food and Drug Administration(FDA) is amending the regulations for food additives to provide for the safe use of feed-grade biuret in lactating dairy cattle feed. This action is in response to a food additive petition filed by ADM Alliance Nutrition, Inc. This rule is effective May 22, 2003; written objections and request for hearing should be submitted by July 23, 2003. In a notice published in the Federal Register of August 28, 2002 (67 FR 55269), FDA announced that a food additive petition (FAP 2248) had been filed by ADM Alliance Nutrition, Inc., 1000 North 30th St., P.O. Box C1., Quincy, IL 62305-7100. The petition proposed to amend the food additive regulations in Part 573 Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the use of feed grade biuret in the diets of lactating dairy cows. The notice of filing provided for a 75-day comment period on the petitioner's environmental information. No substantive comments have been received. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and re delegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows: Section 573.220 Feed-grade biuret is amended by removing paragraph (c)(1)(iii).